IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, *Plaintiff,* v. TOTALLY COOL, INC., a corporation, and MICHAEL J. UHLFELDER, an individual, *Defendants*.	Civil Action No. 1:25-cv-00699

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, on behalf of the United States Food and Drug Administration ("FDA"), for its Complaint alleges:

NATURE OF THE CASE

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Totally Cool, Inc. ("Totally Cool"), a corporation, and Michael J. Uhlfelder, an individual (collectively, "Defendants"), from violating: (a) 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); (b) 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (c) 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States that is not in compliance with 21 U.S.C. § 350g.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

4. On August 23, 2024, Defendant Totally Cool initiated Chapter 11 bankruptcy proceedings. *See In re Totally Cool, Inc.*, 24-BK-17128 (D. Md. 2024). Pursuant to 11 U.S.C. § 362(b)(4), this Court maintains jurisdiction over this litigation notwithstanding pending bankruptcy proceedings because this litigation falls within an exception to the automatic bankruptcy-related stay. *See* 11 U.S.C. § 362(b)(4). A bankruptcy petition "does not operate as a stay" of litigation when, like here, it is brought "by a governmental unit . . . to enforce such governmental unit's . . . regulatory power" including through "a judgment other than a money judgment." *Id.*[1]

DEFENDANTS

5. Totally Cool is a Maryland corporation. The company manufactured, received, prepared, processed, packed, held, and/or distributed frozen ready-to-eat food, including, but not limited to, ice cream novelty products such as cakes, cups, and sandwiches. Ready-to-eat food means any food that is normally eaten in its raw state or any other food, including a processed

[1] The stay exception set forth in 11 U.S.C. § 362(b)(4) applies with equal force where a defendant has been forced to cease its violative conduct due to the pending bankruptcy proceedings. *E,g.*, *In re Commonwealth Companies, Inc*., 913 F.2d 518, 522 (8th Cir. 1990) ("Since the filing of their Chapter 11 petition, the debtor corporations have not engaged in any business activity. They argue that this fact renders § 362(b)(4) inapplicable . . . . [T]he language of § 362(b)(4) 'is unambiguous—it does not limit the exercise of police or regulatory powers to instances where there can be shown imminent and identifiable harm or urgent public necessity.'"); *In re Gandy*, 327 B.R. 796, 806 (Bankr. S.D. Tex. 2005) ("Simply because a defendant has ceased the alleged offensive conduct does not remove a governmental unit's ability to prosecute under its police and regulatory power."); *see also Matter of Commonwealth Oil Ref. Co., Inc.*, 805 F.2d 1175, 1184 (5th Cir. 1986); *In re Emerald Casino, Inc.*, 2003 WL 23147946, at *6 (N.D. Ill. Dec. 24, 2003).

food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. 21 C.F.R. § 117.3. These products were manufactured at Totally Cool's facility located at 38 Gwynns Mill Court, Owings Mills, Maryland 21117 (the "Facility" or "Defendants' Facility"), within the jurisdiction of this Court.

6. Defendant Michael J. Uhlfelder is the President, Chief Executive Officer, and owner of Totally Cool. Defendant Uhlfelder was involved in daily operations at the Facility, and was responsible for maintaining equipment; hiring, managing, and firing employees; overall plant operations; and detecting, preventing, and correcting violative conditions at the Facility. Defendant Uhlfelder performed his duties at the Facility, within the jurisdiction of this Court.

7. Defendants received one or more components used to manufacture their ice cream products from outside of Maryland. For example, Defendants received ice cream pre-mix from United Dairy, Inc., located in Uniontown, Pennsylvania.

8. Defendants manufactured and distributed their ice cream products throughout the United States under various brand names, including, for example, Friendly's, Abilyn's, Hershey's Creamery Corporation, Schwan's/Yelloh!, Jeni's, Cumberland Farms, and ChipWich. Defendants also distributed their ice cream products as a contract manufacturer to multiple firms, including, but not limited to, Friendly's Ice Cream A & D, located in Worchester, Massachusetts; New Holland Transport Inc., located in Denver, Pennsylvania; and Cold Chain Integrity, located in Erlanger, Kentucky.

PUBLIC HEALTH RISKS ASSOCIATED WITH LISTERIA MONOCYTOGENES

9. *Listeria monocytogenes* ("*L. mono*") is a major pathogen, and one of several bacteria contained within the Listeria species ("*Listeria spp.*"). *L. mono* can cause the disease listeriosis, a disease commonly contracted by consuming food contaminated with the bacterium.

Listeriosis can be serious, even fatal, for vulnerable groups such as the elderly, newborns, and those with impaired immune systems. Complications from the disease can include pneumonia, central nervous system damage, endocarditis, localized abscesses, skin lesions, and conjunctivitis. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriages, stillbirth, and meningitis.

10. *L. mono* can survive and grow even when precautions are taken, such as maintaining food at refrigeration temperatures. *L. mono* can also colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment, and is often found on or in condensation, standing water, floors, food residues, processing equipment, and other niches in facilities.

11. The presence of *L. mono* in a facility where ice cream products are exposed to the processing environment allows for contamination of ice cream products and presents a serious danger to public health. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and eliminate niches where *L. mono* can become established, grow, and persist.

DEFENDANTS' VIOLATIONS

12. Defendants' ice cream novelty products are food within the meaning of the Act, 21 U.S.C. § 321(f).

13. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Insanitary conditions include the presence of bacteria such as *L. mono*.

14. To prevent insanitary conditions, food manufacturers must adhere to FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls

("CGMP") regulations (21 C.F.R. Part 117), which establish basic practices and conditions for food manufacturing operations. Food may be deemed adulterated within the meaning of 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with these regulations. 21 C.F.R. § 117.1(a)(1).

15. Defendants have violated the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or been rendered injurious to health. The insanitary conditions include, but are not limited to, the persistent presence of *L. mono* at Defendants' Facility and Defendants' failure to comply with the CGMP regulations.

16. Defendants have violated the Act, 21 U.S.C. § 331(k) by causing articles of food, within the meaning of 21 U.S.C. § 321(f) that Defendants hold for sale after shipment of one or more of their components into interstate commerce, to become adulterated under 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or been rendered injurious to health. The insanitary conditions include, but are not limited to, the persistent presence of *L. mono* at Defendants' Facility and Defendants' failure to comply with the CGMP regulations.

17. Defendants have violated the Act, 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States that is not in compliance with 21 U.S.C. § 350g, which requires the owner, operator, or agent in charge of a facility to, among other things, evaluate the hazards that could affect food manufactured, processed, packed,

or held by such facility, and identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under 21 U.S.C. § 342. As set forth in greater detail below, Defendants' food safety plans did not identify and consider recontamination with environmental pathogens as a hazard, in violation of 21 U.S.C. § 350g and 21 C.F.R. § 117.130(c)(2).

18. FDA found *L. mono* in Defendants' Facility in June 2024 and has determined that the same strain of *L. mono* has persisted in Defendants' Facility since at least 2017. FDA also determined, based on recent inspectional findings, that Defendants operated their food manufacturing facility under insanitary conditions and failed to follow the food CGMP regulations in 21 C.F.R. Part 117.

FDA'S 2024 INSPECTION OF DEFENDANTS' FACILITY

19. FDA conducted an inspection of Defendants' Facility between May 20 and July 1, 2024 (the "2024 inspection"). During this inspection, FDA collected an environmental sample from Defendants' Facility, consisting of 70 subsamples, 11 of which tested positive for *L. mono* at locations throughout the Facility's processing environment, including on food contact surfaces.

20. As set forth in greater detail below, some of the environmental subsamples taken at the Facility during the 2024 inspection that tested positive for *L. mono* matched a strain of *L. mono* identified through environmental sampling taken during previous inspections of Defendants' Facility in 2019 and 2017, which indicates the presence of a persistent, resident *L. mono* strain in Defendants' Facility.

21. During the 2024 inspection, FDA investigators also observed that Defendants failed to comply with the CGMP regulations in multiple ways, including, but not limited to:

a. Condensate on various lines in Defendant's Facility while manufacturing ice cream products, for example, condensate dripping onto a food contact conveyer while ice cream sandwiches were being assembled, in violation of 21 C.F.R. §§ 117.35(a), 117.35(d), 117.80(a)(4), 117.80(c)(2), (6), and (7). Condensation is a concern because it introduces water into the production environment, which, in turn, increases the potential for environmental pathogens, such as *L. mono*, to grow;

b. Defendants' employees using water hoses to spray the floor in the vicinity of production lines while Defendants were manufacturing ice cream cone and cake products, causing aerosolized spray to travel over portions of the lines that contact the products being manufactured, in violation of 21 C.F.R. §§ 117.80(a)(4) and 117.80(c)(2), (6), and (7);

c. Standing, pooled water and/or product debris on the Facility's production floor and excessive product material on equipment surfaces/framework and on floors, including in areas heavily trafficked by production staff and carts, thus facilitating the potential spread of environmental pathogens within and throughout the Facility, in violation of 21 C.F.R. §§ 117.37(b)(4), 117.80(a)(4), and 117.80(c)(2);

d. Defendants' employees did not consistently wash hands or change gloves after performing tasks/activities where they handled/touched unclean surfaces before returning to their workstations and touching food contact surfaces or handling exposed ice cream products, in violation of 21 C.F.R. §§ 117.10(b)(3) and (5); and,

e. Defendants failed to properly identify hazards, such as recontamination with environmental pathogens in their food safety plans for their ice cream products, or to incorporate into those plans appropriate preventive controls at process steps where the products are exposed to the environment, as required by 21 U.S.C. § 350g and 21 § C.F.R. 117.130(c)(2).

For example, Totally Cool's environmental monitoring program was inadequate because, among other things, the number of samplings and the frequency of sampling required by the program were insufficient, and the program lacked sampling and testing of food contact surfaces.

22. At the close of the 2024 inspection, an FDA investigator issued a Form FDA-483 List of Inspectional Observations to Defendant Uhlfelder listing the above-described observations, among others.

FDA'S PREVIOUS INSPECTIONS OF DEFENDANTS' FACILITY

23. FDA inspected Defendants' Facility between May 3-5, 2023 (the "2023 inspection"). During the 2023 inspection, FDA investigators observed violative conditions similar to many of those observed during the 2024 inspection, including, but not limited to:

a. Standing water in various places in the Facility's production area;

b. Employees spraying the Facility's floor with a water hose during ice cream production;

c. Melted ice cream on ice cream cake mold preparation tables and the use of ice cream cake molds that touched the melted ice cream to produce more ice cream cake;

d. Failure to clean and sanitize utensils and equipment as frequently as necessary to protect against contamination of food; and

e. Employees not washing their hands and/or changing gloves appropriately.

24. FDA inspected the Facility twice in 2019. FDA inspected Defendants' Facility between December 17, 2019 to January 7, 2020 (the "second 2019 inspection"). During the second 2019 inspection, FDA investigators observed similar violations, including that the firm's environmental sampling and monitoring standard operating procedures were inadequate because they did not identify sampling locations and frequency of monitoring. In addition, although Totally Cool identified positive *Listeria spp*. findings using in-house testing kits in November 2019, it had

no records documenting it had taken any corrective actions in response to those findings, further demonstrating that the firm lacked adequate written sanitation controls and verification procedures for environmental monitoring. At the close of the inspection, FDA issued a Form FDA-483 List of Inspectional Observations to Defendant Uhlfelder, listing the above-described violations, and discussed these observations with him. Although not included on the Form 483, FDA investigators also observed condensation in the production environment and a cracked floor in disrepair in the production area, a condition considered not cleanable and that is commonly identified as a harborage area for environmental pathogens, including *L. mono*.

25. FDA also inspected the Facility on August 5-6, 2019 (the "first 2019 inspection"), during which FDA investigators collected an environmental sample consisting of 50 subsamples. FDA laboratory analysis revealed the presence of *L. mono* in four of the 50 subsamples collected from surfaces within the production environment, including one from the floor area that was found in disrepair during the second 2019 inspection described above.

26. A non-pathogenic Listeria species, *L. seeligeri*, was detected in three subsamples collected during the first 2019 inspection. Although *L. seeligeri* is a non-pathogenic strain of Listeria, it is an "indicator organism," meaning it provides evidence that *L. mono*, a pathogenic organism, could survive under similar physical, chemical, and nutrient conditions. In addition, the presence of indicator organisms demonstrates inadequate sanitation practices within the production facility and environmental conditions which could support the growth and survival of *L. mono*.

27. FDA inspected Defendants' Facility on June 12-14, 2017 (the "2017" inspection"), during which FDA investigators collected an environmental sample consisting of 66 subsamples. FDA laboratory analysis revealed the presence of *L. mono* in one of the subsamples collected from

a surface within the production environment. FDA notified Totally Cool via a phone call on October 30, 2019 that FDA detected *L. mono* in subsamples taken during the 2017 inspection and the first 2019 inspection.

FDA'S LABORATORY ANALYSIS AND RESULTS

28. Whole Genome Sequencing ("WGS") utilizes a DNA sequencing instrument to obtain the genomic sequence of the DNA of bacteria (such as *L. mono*) isolated from a collected sample ("isolate"). By determining the genomic sequence of a bacterial isolate, WGS allows for high-resolution genetic comparisons between bacterial isolates. As a result, scientists can determine whether two isolates represent the same strain (a genetically distinct lineage) of bacteria.

29. A resident strain of bacteria exists when a strain of bacteria is present in a facility over a period of time. The genetic relatedness of isolates combined with additional data such as the collection time and location of the samples allows scientists to assess whether a resident strain of bacteria exists in a particular location. An analysis of WGS data indicating that the same strain of bacteria was isolated from multiple samples from the same facility over a period of time implies the presence of a resident strain. The existence of a resident strain of bacteria in a particular location establishes a persistent presence of bacteria at that location. The continuing presence of a resident strain of bacteria in a food processing facility indicates that the facility's prior previous sanitation efforts have been ineffective in eradicating that resident strain of bacteria from that facility.

30. In or around June 2024, FDA used WGS to compare the positive *L. mono* isolates collected from the subsamples taken from the Facility during the 2024, 2019, and 2017 inspections, and to all other *L. mono* isolates contained in a public database maintained by the National Center for Biotechnology Information ("NCBI").

31. FDA's analysis of the WGS data revealed a strain detected in certain isolates collected from subsamples taken from the Facility in 2024 matched a strain detected in 2017 and 2019, demonstrating that a resident strain of *L. mono* has been present in Defendants' Facility since at least 2017.

32. In addition, the WGS data identified a match between the resident strain in Defendants' Facility with a clinical isolate from a patient in 2015 identified in the NCBI database. When a pathogen isolate found in a food manufacturing facility matches a pathogen isolate from an ill patient, the match implies that the pathogen strain in the facility is capable of causing illness. Accordingly, because the isolates collected from Defendants' Facility matched the clinical isolate from the NCBI database, FDA has concluded that the resident strain of *L. mono* in Defendants' Facility is capable of causing illness.

POST-2024 INSPECTION ACTIONS

33. On June 24, 2024, during the 2024 inspection, Totally Cool recalled multiple brands of ice cream products potentially contaminated with *L. mono*.

34. On July 8, 2024, FDA suspended the food facility registration of Totally Cool after determining that food manufactured, processed, packed, or held by the Facility has a reasonable probability of causing serious adverse health consequences or death to humans (the "suspension order"). A company without a food facility registration cannot distribute any food products in interstate or intrastate commerce. 21 U.S.C. § 350d(b)(4). The suspension order remains in effect. Although Defendants and FDA have exchanged correspondence concerning Defendants' proposed corrective action plans since the food facility registration was suspended, Defendants have not demonstrated corrections sufficient for FDA to vacate the order pursuant to 21 U.S.C. § 350d(b)(3)(B).

35. The United States believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), 331(k), and 331(uu). While Defendants are prohibited from importing or exporting food into the United States from the Facility, offering to import or export food into the United States from the Facility, or otherwise introduce food from the Facility into interstate or intrastate commerce in the United States due to the FDA's suspension order, unless restrained by an order of this Court, nothing would prevent Defendants from resuming operations at a different facility in the future. Given Defendants' repeated violations, which resulted in the presence of a persistent strain of *L. mono* at the Facility, an injunction is necessary to prevent future violations.

COUNT I
Violations of 21 U.S.C. § 331(a)
Against Defendants

36. Paragraphs 1 through 35 are incorporated as if set forth herein.

37. Defendants have violated 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

COUNT II
Violations of 21 U.S.C. § 331(k)
Against Defendants

38. Paragraphs 1 through 37 are incorporated as if set forth herein.

39. Defendants have violated 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

COUNT III
Violations of 21 U.S.C. § 331(uu)
Against Defendants

40. Paragraphs 1 through 39 are incorporated as if set forth herein.

41. Defendants have violated 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in the United States that is not in compliance with 21 U.S.C. § 350g.

DEMAND FOR INJUNCTIVE RELIEF

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), cease manufacturing, preparing, processing, packing, and/or distributing food at or from the Facility or at any other current or future location, unless and until Defendants bring their manufacturing, preparing, processing, packing and/or distributing operations for food into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) from directly or indirectly from violating: (a) 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); (b) 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C.

§ 321(f) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (c) 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States that is not in compliance with 21 U.S.C. § 350g;

III. Order that FDA be authorized to inspect Defendants' place of business and all records relating to the manufacturing, receiving, preparing, processing, packing, and/or distributing articles of food to ensure continuing compliance with the terms of the injunction, the costs of such inspection to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 3rd day of March, 2025.

PHILIP A. SELDEN
Acting United States Attorney
District of Maryland

By: */s/ Jessica Dillon*
Jessica Dillon
Assistant United States Attorney
36 S. Charles Street 4th Fl.
Baltimore, MD 21201
Tel.: (410) 209-4892
Email: Jessica.Dillon@usdoj.gov

YAAKOV M. ROTH
Acting Assistant Attorney General
U.S. Department of Justice

MICHEAL GRANSTON
Deputy Assistant Attorney General
Consumer Protection Branch

AMANDA N. LISKAMM
Director
Consumer Protection Branch

LISA K. HSIAO
Senior Deputy Director, Civil Litigation
Consumer Protection Branch

ALAN PHELPS
Deputy Director
Consumer Protection Branch

By: */s/ Sarah Williams*
SARAH WILLIAMS
Senior Trial Attorney
Consumer Protection Branch
U.S. Dep't of Justice, Civil Division
450 Fifth Street, N.W., 6th Floor, South
Washington, D.C. 20001
Tel.: (202) 616-4269
Email: Sarah.Williams@usdoj.gov

OF COUNSEL:

ROBERT FOSTER
Deputy General Counsel

U.S. Department of Health and Human Services
Chief Counsel
Food and Drug Administration

SHANNON M. SINGLETON
Deputy Chief Counsel for Enforcement

TRACEY C. ALLEN
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Tel.: (240) 402-9862
Email: Tracey.Allen@fda.hhs.gov